

Remarks/Arguments

A favorable reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

By the foregoing amendments to the specification, the title has been changed to one which more aptly describes the subject matter of the instant claims, and editorial errors noted have been corrected.

Claims 1-10 were presented for examination, and Claims 1-3 and 10-12 are now in the case.

Claims 4, 5, 7 and 8 have been cancelled without replacement.

Claim 6 has been cancelled and re-written in more acceptable form as "new" Claim 11.

Claim 9 has been cancelled and replaced by "new" Claim 12.

Claim 10 has been amended to correct an editorial error.

Applicant acknowledges the fact that the "initial" prior art search and then the "expanded" prior art search conducted by the Examiner failed to uncover anything relevant and, accordingly, the requirement for restriction was withdrawn.

The Examiner has rejected Claims 7 and 8 under the second paragraph of 35 U.S.C. §112 as being indefinite and under 35 U.S.C. §101 as being improper process claims. Since Claims 7 and 8 have been cancelled, this rejection is believed to have been mooted.

In addition to requiring an editorial correction in the preamble to Claim 9, the Examiner has rejected said claim under the first paragraph of 35 U.S.C. §112 for lack of enablement. Although acknowledging that the specification is enabling for treating headaches, the Examiner contends that it does not enable one skilled in the art to practice the invention for the myriad of uses embraced by the claim.

First of all, it appears that the Examiner has overlooked the fact that the instant specification contains a test method and data which establishes the usefulness of the instantly claimed compounds in treating anxiety (see, in this connection, Page 7, lines 17-22).

Secondly, since Claim 9 has been replaced by "new" Claim 12, this rejection is believed to have been overcome. However, to the extent that this rejection has not been overcome by the cancellation of Claim 9 and its replacement with "new" Claim 12, then this rejection is traversed.

Since the instant specification discloses a test method which establishes the usefulness of a compound as a CRF₁ antagonist, coupled with the test results set forth on Page 7, lines 1, 2, 21 and 22, it is clear that all of the compounds of the instant claims exhibit CRF₁ antagonistic activity and, therefore, share the same pharmacological reactivity. Accordingly, there can be no question that one skilled in the art would conclude that all of the compounds embraced by the instant claims would be useful in treating all diseases responsive to the antagonism of CRF₁ receptors, i.e., those disclosed in the instant specification, those disclosed in the literature and heretofore undisclosed indications which are mediated by CRF₁ antagonism.

One further point is that Applicant is entitled to protection commensurate with his discovery. In *In re Johnson et al.*, 194 USPQ 187, the CCPA held that the intention of the statute is not that an Applicant be given as little protection as possible, but rather that he be given as much protection as possible. Thus, the CCPA stated:

"To provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts."

To limit the claims to specific indications for which efficacy has been demonstrated would be tantamount to limiting the application to the preferred indications disclosed notwithstanding the clear disclosure of a broader invention. This clearly is not required by the statute. Restriction of the claims to specific indications would be improper, would frustrate the intent of the statute, and would only invite competitors to avoid infringing the patent by following the teachings in the instant specification and substituting a different indication for the preferred embodiment. This is certainly not the "adequate protection" or "effective incentives" contemplated by the statute.

In brief, Applicant has discovered unique and important compounds which bind to CRF₁ receptors and are useful in treating diseases which are responsive to the antagonism of CRF₁ receptors. Accordingly, it is Applicant's belief that one skilled in the art would have no difficulty in using the compounds for that purpose following the teachings of the instant specification. The instant application, therefore, clearly meets the "enablement" requirements of the first paragraph of 35 U.S.C. §112; and, accordingly, the Examiner is respectfully requested to reconsider the rejection of Claim 9, as it now applies to "new" Claim 12, under the first paragraph of 35 U.S.C. §112 and withdraw it.

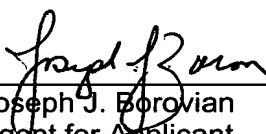
Applicant acknowledges the Examiner's indication that Claims 1-6 and 10 (now Claims 1-3, 10 and 11) are allowed. However, in view of the foregoing amendments and arguments, it is believed that "new" Claim 12 should be allowed as well.

The two rejections of record having been overcome, the instant application is deemed to be in condition for allowance, and an early notice to that effect is earnestly solicited.

Although two "new" dependent claims have been added, six claims were cancelled. Accordingly, no additional fee is necessitated by the added claims. However, since this Amendment will be deemed to have been filed more than five months from, but within six months of, the date of the Office Action, i.e., June 4, 2003, it is respectfully requested that the period for filing a response to said Office Action be extended by three months. Please charge the \$950 fee required by 37 CFR 1.17(a)(3) for a three-month extension of time to Deposit Account No. 19-0134 in the name of Novartis Corporation. In this connection, an additional copy of this page is enclosed.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430/2
East Hanover, NJ 07936-1080



Joseph J. Borovian
Agent for Applicant
Reg. No. 26,631
(862) 778-7801

JJB/lid

Encls.: Additional copy of Page 9
Postcard

Date: December 3, 2003